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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,909	07/21/2003	Eileen Tozer	D1410-2US	7087
29062	7590	02/20/2009	EXAMINER	
VERENIUM CORPORATION Intellectual Property Department P.O. Box 910550 SAN DIEGO, CA 92191-0550				BERTAGNA, ANGELA MARIE
ART UNIT		PAPER NUMBER		
1637				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,909	TOZER ET AL.	
	Examiner	Art Unit	
	ANGELA BERTAGNA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 November 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) See Continuation Sheet is/are pending in the application.
 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,14,15,29,33,35,40,43-45,48,49,87,188,189,207,217,218 and 225-228 is/are rejected.
 7) Claim(s) 33,35,218 and 225-227 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____ .

Continuation of Disposition of Claims: Claims pending in the application are 1,14,15,29,33,35,40,42-45,48,49,51,54,56,58,87,106,107,111,113,116,138,143,174,175,177,182,184,187-190,207,208 and 215-231.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 42,51,54,56,58,106,107,111,113,116,138,143,174,175,177,182,184,187,190,208,215,216,219-224, and 229-231.

DETAILED ACTION

Status of the Application

1. Applicant's response filed on November 21, 2008 is acknowledged. Claims 1, 14, 15, 29, 33, 35, 40, 42-45, 48, 49, 51, 54, 56, 58, 87, 106, 107, 111, 113, 116, 138, 143, 174, 175, 177, 182, 184, 187-190, 207, 208, and 215-231 are currently pending. In the response, Applicant amended claims 1, 29, 33, 188, 218, and 225. Claims 42, 51, 54, 56, 58, 106, 107, 111, 113, 116, 138, 143, 174, 175, 177, 182, 184, 187, 190, 208, 215, 216, 219-224, and 229-231 remain withdrawn as being drawn to a non-elected invention.

The following include new grounds of rejection. Any previously made rejections or objections not reiterated below have been withdrawn. Since the new grounds of rejection presented below were not necessitated by Applicant's amendment, this Office Action is made non-final.

The indicated allowability of claim 189 has been withdrawn in view of the new interpretation of this claim, which causes the previously cited art of Tsien et al. (US 6,140,132) to remain applicable. This issue is discussed in greater detail below.

Claim Objections

2. Claims 33, 35, 218, and 225-227 are objected to because of the following informalities:

- (i) Claim 33 recites "where in" in line 5. It would appear that "wherein" was intended.
- (ii) Replacing "the probe" appearing in lines 2 and 5 of claim 33 with "the nucleic acid probe" is suggested to improve consistency within the claim.

(iii) Replacing “the probe” appearing in line 2 of claim 35 with “the nucleic acid probe” is suggested to improve consistency within the claim.

(iv) In claim 218, replacing “further comprising” with “wherein the process further comprises” is suggested to improve the clarity of the claim.

(v) In claim 225, it appears that “c” should be inserted at the beginning of line 7 and that “d” should be inserted at the beginning of line 8.

(vi) In claims 226 and 227, replacing the phrase “encoding a fluorescent protein comprising the sequence of claim 1” with “comprising the sequence of claim 1 and encoding a fluorescent protein” is suggested to make clearer the fact that the nucleic acid and not the fluorescent protein comprises the sequence of claim 1.

(vii) In claim 227, replacing the phrase “and optionally the tag or reporter sequence comprises” with “wherein the tag or reporter sequence optionally comprises” is suggested to improve the grammar of the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph (Written Description)

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 14, 15, 29, 35, 43-45, 48, 49, 87, 188, 217, 218, and 225-228 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way

as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The central inquiry when considering written description is whether an ordinary artisan would reasonably conclude that Applicant was in possession of the claimed invention at the time of filing (see MPEP 2163 and *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566-67, 43 USPQ2d 1398, 1404-05 (Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998)).

According to Revision I of the Written Description Training Materials (posted 4/11/08 at <http://www.uspto.gov/web/menu/written/pdf>), the following factors should be considered, when evaluating a claim for compliance with the written description requirement: (a) actual reduction to practice, (b) disclosure of drawings or structural chemical formulas (c) sufficient relevant identifying characteristics (d) method of making the claimed invention, (e) level of skill and knowledge in the art, and (f) predictability in the art (see page 1 of the Training Materials).

The instant claims are drawn to isolated nucleic acids that encode a fluorescent polypeptide and are at least 95% identical to SEQ ID NO: 29 and compositions (e.g. vectors, host cells) comprising said nucleic acids. The genus of nucleic acids having at least 95% identity to SEQ ID NO: 29 is very large and includes hundreds of thousands of structurally distinct molecules, each of which may encode a polypeptide having different functional properties. The claims limit this large genus to nucleic acids that encode a fluorescent protein.

The specification teaches the nucleic acid sequence of SEQ ID NO: 29 (see page 17 of the Sequence Listing), and therefore, it contains an actual reduction to practice of one member

within the claimed genus. The specification also discloses nucleic acids having at least 95% identity to SEQ ID NO: 29 (see, for example SEQ ID NO: 17). However, the specification does not disclose those regions of SEQ ID NO: 29 that are critical for conferring fluorescence activity to the encoded protein. There is a high degree of unpredictability in the art regarding structure-function correlations, and even a single nucleotide substitution can abolish the function of the protein encoded by a mutant nucleic acid. Accordingly, the level of skill in the art is high. The claimed nucleic acids do not show a significant level of similarity to other fluorescent proteins known in the art, and the specification does not teach that motifs known to be critical for fluorescence activity in these proteins are present in the proteins encoded by the claimed nucleic acids. As a result, the specification fails to adequately describe the relevant identifying characteristics that are critical for determining whether a giving nucleic acid having at least 95% identity to SEQ ID NO: 29 also has the required functional property of fluorescence. In the absence of such disclosure, it must be concluded that Applicant was not in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 112, 1st paragraph (Enablement)

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 14, 15, 29, 35, 43-45, 48, 49, 87, 188, 217, 218, and 225-228 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404,

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

The Nature of the Invention & Breadth of the Claims

The instant claims are drawn to isolated nucleic acids that encode a fluorescent polypeptide and are at least 95% identical to SEQ ID NO: 29 and compositions (e.g. vectors, host cells) comprising said nucleic acids. The genus of nucleic acids having at least 95% identity to SEQ ID NO: 29 is very large and includes hundreds of thousands of structurally distinct molecules, each of which may encode a polypeptide having different functional properties. The claims limit this large genus to nucleic acids that encode a fluorescent protein.

Guidance in the Specification and Working Examples

The specification teaches the nucleic acid sequence of SEQ ID NO: 29 (see page 17 of the Sequence Listing), and therefore, it contains an actual reduction to practice of one member within the claimed genus. The specification also discloses nucleic acids having at least 95% identity to SEQ ID NO: 29 (see, for example SEQ ID NO: 17). However, the specification does

not disclose those regions of SEQ ID NO: 29 that are critical for conferring fluorescence activity to the encoded protein. There is no discussion in the specification of motifs or regions in SEQ ID NO: 29 that are critical for conferring this required functional property.

The working examples (see pages 155-159) also do not describe the regions of the disclosed nucleic acids that are critical for encoding a functional (*i.e.* fluorescent) protein. In Example 1 cDNA libraries prepared from marine sources were analyzed to identify cDNA clones encoding fluorescent proteins (see pages 155-156). In Example 2 (see pages 156-158), fluorescent proteins were isolated and purified. In Example 3 (see pages 158-159), the excitation and emission properties for a subset of the disclosed fluorescent proteins was determined. However, Examples 1-3 do not provide any discussion of regions of the proteins that are required for fluorescence activity.

State of the Prior Art and Unpredictability

The prior art does not teach isolated nucleic acids that are at least 95% identical to SEQ ID NO: 29 and encode a fluorescent polypeptide. The claimed nucleic acids do not show a significant level of similarity to other fluorescent proteins known in the art, and therefore, the art does not identify regions or motifs in the claimed nucleic acids that are critical for fluorescence activity. There is a high degree of unpredictability in the art regarding structure-function correlations, and it is well established that even a single nucleotide substitution can abolish the function of the protein encoded by the mutant nucleic acid. Therefore, it is highly unpredictable whether or not a given nucleic acid having at least 95% identity to SEQ ID NO: 29 will have

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fluorescence activity, especially since neither the specification nor the art teaches the regions of the protein that are critical for maintaining fluorescence activity.

Quantity of Experimentation

The quantity of experimentation required in this case is immense, because it would require significant study and experimentation to determine whether a nucleic acid having at least 95% identity to SEQ ID NO: 29 also encodes a fluorescent protein. Each different variant nucleic acid would have to be produced via mutagenesis, and the encoded proteins would have to be expressed and characterized functionally. In the absence of any guidance in the specification or the art regarding regions of SEQ ID NO: 29 that are critical for determining fluorescence activity, the ordinary artisan would have little or no starting point for determining whether a given variant of SEQ ID NO: 29 encodes a fluorescent protein. Given the unpredictability in the art regarding the effect of nucleic acid mutations on the functionality of the proteins encoded therefrom, the ordinary artisan would be required to undertake this large quantity of experimentation with little or no guarantee of success.

The Level of skill in the art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, the instant claims are broadly drawn to isolated nucleic acids having at least 95% identity to SEQ ID NO: 29 and that encode a fluorescent protein. Despite the breadth of the claims, the specification only teaches a small number of

nucleic acids falling within the claimed genus and provides no guidance regarding the regions of SEQ ID NO: 29 that are required for the fluorescence activity of the claimed proteins. Thus, given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to determine those regions of SEQ ID NO: 29 required for fluorescence activity, the lack of guidance provided in the specification, balanced only against the high skill level in the art, it is the position of the examiner that the claimed nucleic acid products fail to comply with the enablement requirement.

Claim Rejections - 35 USC § 112, 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 87, 207, and 225 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is indefinite, because it recites the limitation “the nucleic acid sequence” in line

8. There is insufficient antecedent basis for this limitation in the claim.

Claim 87 is indefinite, because it recites the limitation “the immobilized nucleic acid”.

There is insufficient antecedent basis for this limitation in the claim.

Claim 207 is indefinite, because it depends from a canceled claim – claim 206.

Claim 225 is indefinite, because it recites the limitation “the template sequence” in lines 5-6 and the limitation “the template nucleic acid” in line 6. There is insufficient antecedent basis for these limitations in the claim.

Claim 225 is further indefinite, because it is unclear what is intended by the phrase "or a combination" thereof appearing in step (b) of the claim. In particular, it is unclear whether the phrase is intended to mean that a combination of modifying, deleting, or adding of nucleotides to the template is permitted or if the phrase is intended to mean that more than template is used.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Dean et al. (Genome Research (June 2001) 11(6): 1095-1099; newly cited).

Claim 40 is drawn to an amplification primer pair capable of amplifying a nucleic acid comprising a sequence of claim 1.

Dean teaches a composition comprising random hexamer primers (see page 1099). This composition of amplification primer pairs is inherently capable of amplifying a nucleic acid of claim 1.

8. Claim 189 is rejected under 35 U.S.C. 102(b) as being anticipated by Tsien et al. (US 6,140,132).

Regarding claim 189, Tsien teaches an isolated nucleic acid (SEQ ID NO: 7) that comprises *a sequence* as set forth in SEQ ID NO: 29 (see alignment below, where "a sequence"

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encompasses dinucleotides or larger, and therefore, SEQ ID No: 7 of Tsien comprises a sequence as set forth in SEQ ID NO: 29. It is noted that amendment of claim 189 to recite “An isolated, synthetic, or recombinant nucleic acid comprising the sequence set forth in SEQ ID NO: 29” would obviate this rejection.

ALIGN calculates a global alignment of two sequences version 2.0. Please

cite: Myers and Miller, CABIOS (1989) 4:11-17

seq_29 687 nt vs.

tsien_cfp_seq_7 720 nt

scoring matrix: DNA, gap penalties: -16/-4

10 20 30 40

seq. 29 ATG-----AAGGGGGTGAAG-----GAAGTAATGAAGATCAGTCGGAGATGGAC

```

seq_29      ATGGGTGAGCAAGGGCGAGGAGCTGTTACCGGGGTGGTGCCATCCTGGTCAGCTGGAC
            ::::::::::::::::::::: ::::: ::::: ::::: ::::: ::::: ::::: ::::: :::::
tsien_cfp_se ATGGGTGAGCAAGGGCGAGGAGCTGTTACCGGGGTGGTGCCATCCTGGTCAGCTGGAC

```

50 60 70 80 90 100

sec. 29 TGGACTGTAAACGGCGACAAATTAAAGATCACTGGGGATGGAACAGGGAGAACCTTACGAA

```

seq_29    TGCAC1G1TAAACGGCGACAATTTAAGATCACTGGGGATGGAACAGGGAAACCTTACGAA
          :: :: ::::::: :::: :: : : : : : : : : : : : : : : : : : : : :
tsien cfp se GGCAGCTAAACGGCCACAGGTTCAGCGTGTCCGGCGAGGGCGAGGGCGATGCCACCTAC

```

110 120 130 140 150 160

... 110 120 130 140 150 160
GGAGGAGAGAGTTAATGCTTACAGAGAGCAACGAAACGCTCTGAACCTTTCTTGCAAT

```

seq_29      GGAACACAGACTTACATCTACAGAGAAGGAAGGCAGCCTCTGACGTTTCTTCGAT
            :: : : :: : : : : : : : : : : : : : : : : : : : : : : : : :
tsien_cfp_se GGCAAGCTGACCCCTGAAGTTCATCTGCACCACCGGCAAGCTGCC--CGTGCCCTGGCCCA

```

170 180 190 200 210 220

seq_29 GTATTGACACCAGCATTCACTATGGAAACCGTACATTCAACCAAATACCCAGGCAATAT-
 : : : ::
target_sfp_20 CCCTGCCTGACCGACGCTGACGTCCCCCCTGCACTTC-TTGACGCCCTACCCCCGACGACATC

230 240 250 260 270

seq_29 -ACCAG----ACTTTTCAAGCAGACCGTTCTGGTGGCGGGTATACCTGGGAGCGAAAA
 : ::: ::::: ::::::: :: : : : ::: :: : ::::::: :

240 250 260 270 280 290

280 290 300 310 320 330

seq_29 ATGACTTATGAGGACGGGGCATAAGTAACGTCCGAAGCGACATCAGTGTGAAAGGTGAC
::: :: ::::: ::::: ::::: ::::: ::::: ::::: ::::: ::::: ::::: ::::: :::::

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	340	350	360	370	380	390
seq_29	TCTTTCTACTATAAGATTCACTTCA--CTGGCGAGTTCCCTCCTCATGGTCCAGTGATGC					
	:	::	:	::	:	::
tsien_cfp_se	AC--CCTGGT---GAACCGCATCGAGCTGAAGGGCATCGACTTCAAGGAGGACGGCAAC					
	360	370	380	390	400	
	400	410	420	430	440	
seq_29	AGAGAAAGACAGTAAAATGGGAGGCCATCCACTGAAGT---AATGTATGTT----GACGA					
	:	::	::	::	::	::
tsien_cfp_se	ATCCTGGGGCAC-AAGCTGGAGTACAACATACAGCCACAACGTCTATATCACCGCCGA					
	410	420	430	440	450	460
	450	460	470	480	490	500
seq_29	CAAGAGTGACGGTGTGCTGAAGGGAGATGTCAACATGGCTCTGTTGCTTAAAGATGGCCG					
	::::	:	:	::	:	::
tsien_cfp_se	CAAGCAGAAGAACGGCATCAAGGCCACTTCAAGATCCGCCACAACATCGAGGACGGCAG					
	470	480	490	500	510	520
	510	520	530	540	550	560
seq_29	CCATTGAGAGTTGACTTTAACACTTCTACATACCCAA-GAAGAAGGTC--GAGAATAT					
	:	:	::	::	:	::
tsien_cfp_se	CGTGCAGCTGCCGACCCTACCAAGCAGAACACCCCCATGGCGACGGCCCCGTGCTGCT					
	530	540	550	560	570	580
	570	580	590	600	610	620
seq_29	GCCTGACTACCATTATAGACCACCGCATTGAGATTCTGGCAA---CCCAGAACGACAA					
	:::	:::	::	::	::	::
tsien_cfp_se	GCCCGACAACCACTACCT-GAGCACC-CAGTCCGCC-CTGAGCAAAGACCCAACGAGAA					
	590	600	610	620	630	640
	630	640	650	660	670	
seq_29	GC-CGGTCAAGCTGTAC----GAGT--GTG-CTGTAGCTCGCTAT---TCTCTGC-TGC					
	::	:::	::	::	::	::
tsien_cfp_se	GCGCGATCACATGGTCTCTGCTGGAGTCGTGACCGCCGC-CGGGATCACTCTGGCATGG					
	650	660	670	680	690	700
	680					
seq_29	CTGAGAAGAACAAAGTAG					
	:::	:::	::	::	::	::
tsien_cfp_se	ACGAGCTGTACAAGTAA					
	710	720				

Response to Arguments

9. Applicant's arguments filed on July 24, 2008 have been considered, but they are moot in view of the new grounds of rejection presented above.

Conclusion

10. No claims are currently allowable. Claims 1, 14, 15, 29, 33, 35, 43-45, 48, 49, 87, 188, 217, 218, and 225-228 are free of the art, but they have been rejected for failing to comply with the requirements of 35 U.S.C. 112.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 9- 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/GARY BENZION/
Supervisory Patent Examiner, Art Unit 1637